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Attention: Beverly Friedman

This letter clarifies the communication of March 29, 2011 regarding application for patent term extension of U.S. Patent No. RE38,115 under 35 U.S.C. § 156. That letter incorrectly identified on the top of page 2,

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Since it appears to the USPTO that each of the active ingredients in NUEDEXTA has been previously approved by FDA as described in the March 29, 2011 letter, the patent does not appear to be eligible for extension because the permission for the commercial marketing or use of NUEDEXTA fails to meet the requirements of §156(a)(5)(A).

Thus, our review of the application to date indicates that the subject patent would NOT be eligible for extension of the patent term under 35 U.S.C. § 156.

Furthermore, no determination has been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, as such, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

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